REMARKS

Claims 11-15, 21 and 22 were pending. Claims 11 and 12 are amended. New claim 23 is added. Support for the amendments and the new claims is found throughout the specification. Therefore, it is believed that no new matter has been added. Claims 11-15 and 21-23 are pending. No claim is allowed.

Applicants gratefully acknowledge the entry of the amendment filed on September 9, 2004.

Rejection Under 35 U.S.C. §§ 101 and 112

Claims 11-15, 21 and 22 remain rejected under 35 U.S.C. §§ 101 and 112, first paragraph as allegedly lacking a specific and substantial utility or a well established utility for reasons of record. Briefly, the Examiner alleges that the declaration of Dr. Mattson is insufficient to overcome the rejection because the data presented does not provide information on the activity or function of the protein, and thus does not provide a utility for the protein or an antibody to the protein. The Examiner asserts that the elevation of RANKL transcript levels in inflammation provides no information on its function, providing no information on how RANKL functions. According to the Examiner, the data submitted by Dr. Mattson using SEQ ID NO:17 does not provide a prediction that two other variants, SEQ ID NOs:15 and 19 will also be upregulated in inflammation. Applicants traverse this rejection for reasons of record as well as those discussed below.

Applicants respectfully submit the objective evidence demonstrating the sufficiency of *all* of the disclosed utilities for RANKL has not been addressed. More specifically, the Action dated November 30, 2004 contains *no* reference to or acknowledgement of the post-filing publication of Sinha and Chaudhaury, its findings, and the arguments within the preliminary amendment filed September 9, 2004. *See* Exhibit A (included herein for the Examiner's convenience). Sinha demonstrates a *second* disclosed utility for RANKL (or the X-linked ectodermal dysplasia receptor), *i.e.*, the induction of apoptosis. The instant specification specifically discloses RANKL as a regulator of cell proliferation or development. *See* the specification at page

32, lines 19-21. In particular, the specification cites the ability to kill cells (*e.g.*, induce apoptosis), affect differentiation, and cause changes in cytokine expression as specific examples of regulating cellular proliferation - all functions that are *characteristic* of TNF ligand/receptor family members. *See, e.g.,* the specification at page 32, lines 22-35. The specification discloses that the RANKL-specific antibodies may be useful in the treatment of diseases associated with abnormal proliferation including cancerous conditions and degenerative conditions. *See* the specification at page 57, lines 8-25. The work of Sinha confirms the specific, substantial, and credible utility for RANKL as a protein that regulates cell proliferation and thus useful in conditions associated with abnormal proliferation as disclosed in the instant specification.

Applicants further submit that the Examiner has taken the position that the data supporting the disclosed utility must be of a particular character. Alternatively stated, the Examiner appears to suggest that the data must show how RANKL is functioning. However, such is not the standard. The standard is merely that the asserted utility is specific, substantial, and credible. *See* MPEP § 2107. There is *no* requirement that a protein function be defined. The specification discloses that RANKL as useful in modulating a specific disease, *i.e.*, inflammation. Inflammation is a recognized disease and the demonstration of its role with the TaqMan® data provided by Dr. Mattson confirms its credibility. Li's determination of that IL-1β in the exemplary article may be involved in ischemic brain tolerance is sufficient to meet the minimal utility requirement, as a person of skill in the art would believe it is more likely than not that IL-1β played a role in ischemic brain tolerance based on Li's data. Applicants note that "[usefulness] in patent law, and in particular, in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." *In re Brana*, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). To demand that each protein's function be fully characterized would effectively preclude the patentability of many new proteins and introduce unnecessary ambiguity into a minimal threshold for utility determinations established by legal precedent.

Finally, the use of SEQ ID NO:17 alone fails to render Dr. Mattson's declaration inapplicable to the related sequences of SEQ ID NOs:15 and 19. While the Examiner speculates that these sequences are splice variants, the Examiner provides no scientific evidence to support her position. Nonetheless, in an effort to expedite prosecution and prepare the claims for allowance, or

in the alternative, appeal, the amended claims relate to SEQ ID NO:17 alone. These amendments are made without prejudice, and Applicants expressly reserve the right to pursue this subject matter in a related application.

In view of the above, the basis for the rejection may be removed.

Rejection Under 35 U.S.C. §§ 102 (e) and 103 (a)

Claims 11-15, 21 and 22 are rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by Goddard et al., U.S. Patent No. 6,534,061 for reasons of record. Claims 11-14, 21 and 22 are rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by Goddard et al., U.S. Published Application 20030092044, effective filing date April 12, 1999 for reasons of record. Claim 15 is rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Goddard et al., U.S. Patent No. 6,534,061 in view of Akita et al., U.S. Patent No. 5,968,511 or Goddard et al., U.S. Published Application 20030092044 in view of Akita et al., U.S. Patent No. 5,968,511 for reasons of record. Applicants traverse this rejection.

Applicants submit that Goddard is not a proper reference under 35 U.S.C. § 102 (e) for reasons of record. Again, Applicants have met their burden with regards to the utility requirement for both the protein and the nucleic acid of the RANK-like protein, and therefore, Applicants maintain their traversal of the Examiner's refusal to properly award a priority date of at least September 11, 1998. As the priority date is properly at least September 11, 1998, neither Goddard publication is properly a reference under 35 U.S.C. § 102 (e) against the instant application.

In view of the above, Applicants submit that the basis of the rejection may be removed.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000401. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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